News from the EMA

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One Health: a joint framework for action published by five EU agencies

May 7, 2024

Today, the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA), and the EMA published a joint framework for action to strengthen cooperation to support the implementation of the One Health agenda in the European Union (EU).

One Health recognises the complex interplay between human, animal, and plant health, food safety, the climate crisis, and environmental sustainability. Implementing this approach across different sectors will be key to making the EU and its Member States better equipped to prevent, predict, detect, and respond to health threats. It will mitigate the impact and societal cost of such threats, or even prevent their emergence, while also helping to reduce human pressures on the environment and safeguarding key societal needs such as food security and access to clean air and water.

A cross-agency task force will work on implementing the joint framework for action over the next three years (2024-2026), focusing on five strategic objectives: strategic coordination, research coordination, capacity building, stakeholder engagement and joint inter-agency activities. This will ensure that the scientific advice provided by the agencies is increasingly integrated, that the evidence base for One Health is strengthened and that the agencies are able to contribute with a common voice to the One Health agenda in the EU.

In November 2023, the five EU agencies that provide scientific advice on the environment, public health and food safety topics issued a joint statement expressing their shared commitment to supporting the One Health agenda in Europe. On the occasion of the launch of the joint framework for action, the Executive Directors of the five EU agencies reinforced their commitment to the One Health approach in a joint video statement.

European medicines network designated as WHO Listed Authority

May 20, 2024

The European Medicines Regulatory Network (EMRN) has been designated as WHO Listed Authority (WLA) by the World Health Organisation (WHO). This means that the network, composed of the European Commission, EMA and the 30 national authorities of the European Economic Area Member States, are recognised as meeting international regulatory standards, guidelines and practices. The assessment process was facilitated by the Steering Group for Benchmarking of European Medicines Agencies (BEMA SG).

The EMRN is the cornerstone of EMA's work and success. The Agency operates at the heart of the network, coordinating and supporting interactions of national competent authorities for human and veterinary medicines in Europe. The designation as WLA follows a comprehensive assessment by WHO. It covers each individual regulatory authority of the EMRN, as well as the EMRN overall, which is recognised as a single entity and has also been designated as a "regional regulatory system".

Collaboration with WHO is specifically highlighted in the legislation establishing EMA. The WLA designation complements the cooperation between these organisations in the context of global public health networks and initiatives.

A WLA is a regulatory authority or a regional regulatory system which has been judged to comply with all the indicators and requirements specified by WHO. The WLA initiative is being implemented by WHO to promote access to and supply of safe, effective, and high-quality medical products. It ensures optimal use of limited global regulatory resources by facilitating reliance on the work and decisions of trusted regulatory authorities. The reliable and highly performing WLAs listed by WHO can be used as a reference point by regulatory authorities that lack the resources to perform all necessary regulatory functions, or which have not yet reached higher maturity levels for medical product oversight. Overall, the WHO Listed Authority framework is expected to promote confidence and reliance, whilst fostering regulatory convergence, harmonisation of approaches and international cooperation.

Medical devices: New guidance for industry and notified bodies

May 21, 2024

A new revision of the guidance has been published and is available to applicants, marketing authorisation holders, and notified bodies of medical devices. This question-and-answer document[1] provides practical considerations on the implementation of the medical devices and in vitro diagnostic regulations for combinations of medicinal products and medical devices.

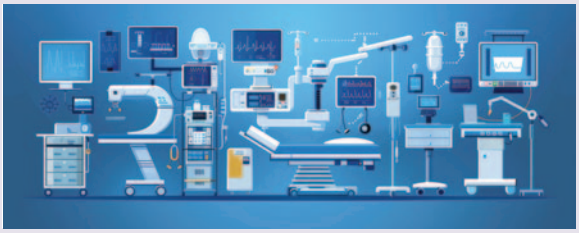
Products that combine a medicinal product (or substance) and a medical device are regulated either under the pharmaceutical framework or the medical device framework, depending on their main mode of action. The revision is based on the experience gained since the implementation of the new regulations and actual cases encountered. The document covers regulatory and procedural guidance for:

- integral drug-device combinations (medical devices that form an integral product with a medicine, such as pre-filled syringes) and their lifecycle management
- medicinal products that include a medical device in their packaging (referred to as co-packaged) and how these should be labelled
- the consultation procedure for medical devices with an ancillary medicinal substance (a substance that supports the proper functioning of the device)
- the consultation procedure for companion diagnostics, diagnostic tests that are essential for the correct use of a specific medicine.

The guidance is provided to support the application of the regulations on medical devices (Regulation (EU) 2017/745) and on in vitro diagnostic devices (Regulation (EU) 2017/746). These two regulations changed the European legal structure for medical devices, introducing new responsibilities and requirements for EMA and national competent authorities in the assessment of certain categories of medical devices used in combination with medicines.

Reference

1. Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746). May 3, 2024; Rev.4 EMA/37991/2019 Human Medicines Division. Available at: Questions & Answers on the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (europa.eu)



First vaccine to protect adults from Chikungunya

May 31, 2024

EMA has recommended granting a marketing authorisation in the European Union (EU) for Ixchiq, the first vaccine in the EU to protect adults 18 years and older against Chikungunya. It is given as a single dose.

Chikungunya (also called CHIK fever) is a viral disease caused by Chikungunya virus (CHIKV), a virus transmitted to humans by infected mosquitoes (primarily Aedes aegypti and Aedes albopictus). Most people infected with CHIKV develop symptoms within 3–7 days. The most common symptoms of acute disease are fever and joint pain. Other symptoms can include headache, muscle pain, joint swelling, or rash. Most patients recover within a week, but some develop joint pain for several months or longer, which can be disabling. A small proportion of patients may develop severe acute disease, which can lead to multiorgan failure and is most often observed in newborns exposed to the virus during childbirth and adults over 65 years old. There is currently no licensed treatment for Chikungunya.

CHIKV infections affect people mostly in the tropics and subtropics, and the majority of countries reporting high disease burden are located in Central and South America. Chikungunya is not endemic in Europe. The majority of cases in the EU concern travellers who were infected outside of mainland Europe. However, there have been sporadic incidents of onward transmission by infected travellers after their return, mainly in Southern Europe where the Aedes. albopictus mosquito is established. Spread of the mosquito due to climate change could lead to cases of Chikungunya in regions so far spared.

Considering the significant global public health implications of this vaccine, Ixchiq was assessed under EMA's OPEN initiative that fosters international collaboration and sharing of scientific expertise to promote global public health. The OPEN framework allowed the World Health Organisation and ANVISA, the Brazilian medicines regulator authority, to participate in the discussions of EMA's Human Medicines Committee (CHMP) and its advisory bodies. Brazil is currently experiencing outbreaks of Chikungunya in a number of regions, reporting over 160,000 cases in the first quarter of 2024.

The CHMP's opinion is largely based on data from a placebo-controlled study that assessed the immunogenicity and safety of the vaccine in adults from 18 years. The immune response was evaluated in 362 participants (266 treated with Ixchiq and 96 with placebo). The clinical efficacy of Ixchiq was inferred from a post-vaccination CHIKV-specific neutralising antibody titre threshold. At 28 days after vaccination, 98.9% of individuals administered Ixchiq had antibody titres against CHIKV above the threshold. At 12 months and 24 months after vaccination, antibody titres above the threshold persisted in 99.5% and 97.1% of individuals administered the vaccine, respectively. Antibody titres will be monitored for up to five years. The CHMP has requested a post-authorisation efficacy study to confirm the effectiveness of Ixchiq in preventing Chikungunya in adults.

The safety profile of Ixchiq is based on pooled data from three completed clinical studies with 3,610 participants with a 6-month follow-up. The most common side effects reported were headache, tiredness, muscle pain, joint pain, fever, nausea, tenderness, and injection site pain. Chikungunya-like adverse reactions are an important identified risk and will be further characterised with post-authorisation safety studies.

Climate change can drive many of the health threats we are facing today. The rise in cases of vector-borne diseases transmitted through mosquitoes such as Chikungunya is a clear example of the impact of climate change on health and reinforces the need for a One Health approach. EMA, together with other EU agencies, has recently published a joint One Health framework for action to support the implementation of One Health in Europe and help build a region better able to prevent, predict, prepare, and respond to emerging public health threats.

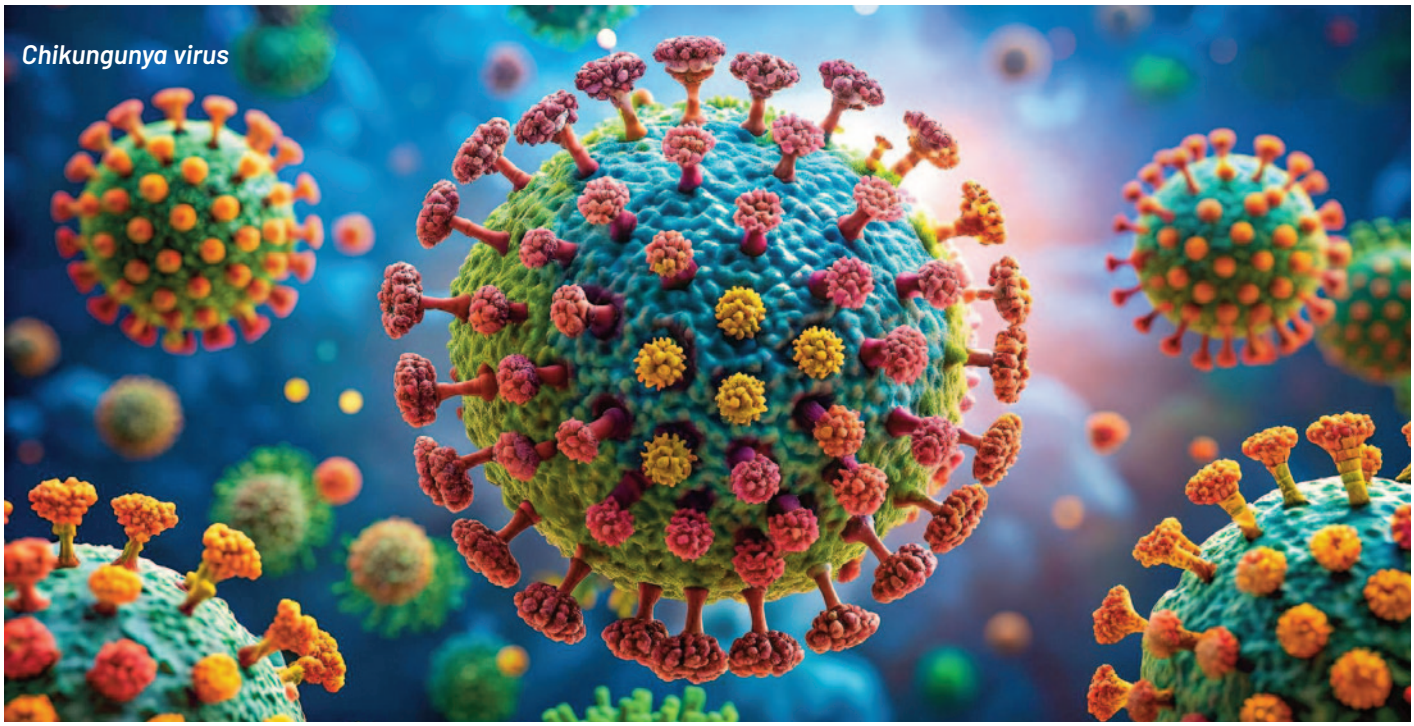


Photo: Freepik

Faster access to clinical trial information in Europe

June 18, 2024

The launch of a new version of the Clinical Trials Information System (CTIS) will allow earlier and more efficient access to information about clinical trials in the European Union (EU) for patients, healthcare professionals, and other stakeholders. This is due to the revised transparency rules that become applicable today in Europe. Several resources have been created to help sponsors understand the revised transparency rules, including a user guide[1] and an overview[2] of which data and documents with key information will be published in CTIS.

CTIS is the single-entry point for the submission and assessment of applications for clinical trials in the EU for sponsors and regulators. The system includes a public searchable database for healthcare professionals, patients, and the general public to deliver the high level of transparency foreseen by the regulation. The authorisation and oversight of clinical trials is the responsibility of EU/EEA Member States while EMA is responsible for maintaining the CTIS. The European Commission oversees the implementation of the Clinical Trials Regulation.

One of the key changes in the new version of CTIS is earlier availability of information on authorised clinical trials. Importantly, the new rules eliminate the previously available deferral mechanism, which allowed clinical trial sponsors to delay publishing certain data and documents for up to seven years after a trial's completion to protect commercially confidential information. Under the new rules, approximately 4,000 clinical trials with issued decisions are now publicly accessible through the CTIS search. The CTIS portal will add approximately 500 newly authorised clinical trials per month. This includes ongoing trials that have been transitioned to CTIS from the Clinical Trials Directive. Over the next few months, additional features will be added to the CTIS public portal to further enhance overall usability.

The updated rules strike a balance between transparency of information and protection of commercially confidential information. They benefit patients, because key clinical trial information, that patients flagged as being most relevant for them, is published early. They also benefit clinical trial sponsors because they introduce process simplifications. Finally, they benefit healthcare professionals because the resulting system is more user-friendly, facilitating access to information on clinical trials and enrolment in clinical trials, and also increasing awareness of possible treatment options.

The revised transparency rules were adopted by EMA's Management Board in October 2023 following a public consultation held between May and June 2023.

References

1. Revised CTIS transparency rules and historical trials: quick guide for users. V. 1.7, updated on 19 July 2024. Available from: https://accelerating-clinical-trials.europa.eu/document/download/a101771b-0be7-492f-b8bd-7f551ffbb7a7_en?filename=Revised%20CTIS%20transparency%20rules%2C%20Interim%20period%20%26%20Historical%20trials_quick%20guide%20for%20users_1.pdf
2. Annex I: Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS). June 18, 2024; EMA/194159/2023

Photo: Freepik

Positive CHMP opinion on first-in-class medicine to treat pulmonary arterial hypertension

June 28, 2024

EMA has recommended granting a marketing authorisation in the European Union (EU) for Winrevair (sotatercept) to treat adult patients with pulmonary arterial hypertension (PAH), in combination with other specific PAH therapies, to improve exercise capacity.

Pulmonary arterial hypertension is a rare, long-term, debilitating and life-threatening condition in which patients have abnormally high blood pressure in the arteries in the lungs. Many patients experience breathing difficulty that limits their physical activity. Despite approved therapies, long-term prognosis remains poor: it is estimated that around 50% of patients will die within five to seven years after diagnosis.

Winrevair (sotatercept) is the first activin signalling inhibitor therapy approved to treat PAH. In the body, proteins called activins attach to a receptor called ActRIIA to stimulate the growth of cells that make up the blood vessels. These receptors are over-active in patients with PAH. Sotatercept is a copy of ActRIIA, and because it also attaches to activins, it prevents them from activating the receptor. In this way, sotatercept regulates the growth of new blood vessel cells in the lungs. This leads to reduced narrowing and thickening of the blood vessels, thus improving the symptoms of the disease.

The medicine is administered once every 3 weeks as a single injection under the skin and may be administered by patients or caregivers with guidance, training and follow-up from a healthcare provider.

The recommendation is based on the results of a randomised, double-blind, placebo-controlled, multicentre clinical trial that evaluated the efficacy and safety of sotatercept in 323 adults with PAH on stable treatment for more than 90 days with background PAH therapy (monotherapy or combination therapy).

Results of the trial show that patients on sotatercept had significantly improved exercise capacity measured by how far they were able to walk within six minutes at the start of treatment and after 24 weeks. This increase is considered clinically relevant as it compares to the results of the pivotal study of already-authorised products for PAH.

The most common side effects associated with this medicine are headache, nose bleeds, rash, tiny blood vessels that look like pink or red lines on the skin (telangiectasia), diarrhoea, dizziness and redness. Although Winrevair is generally well tolerated, there have been rare reports of serious side effects affecting the blood, such as increased blood pressure, low platelet count (thrombocytopenia) which can increase the risk of bleeding, and increased haemoglobin concentrations which can lead to thromboembolic events such as a stroke. The last two conditions listed are considered manageable by modifying the dose of Winrevair.

Winrevair was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs.

The opinion adopted by the CHMP is an intermediary step on Winrevair's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

First nasal adrenaline spray for emergency treatment against allergic reactions

June 28, 2024

EMA's Human Medicines Committee (CHMP) has recommended granting a marketing authorisation in the European Union for Eurneffy (epinephrine), the first medicine to be taken through the nose for the emergency treatment of allergic reactions (anaphylaxis).

According to the European Academy of Allergy and Clinical Immunology (EAACI), allergy is the most widespread chronic disorder in Europe, with 150 million Europeans affected in 2015. Around 20% of people suffering from severe allergic conditions live in fear every day of an anaphylactic shock or of dying from an allergic reaction.

Anaphylaxis is the most severe form of allergic reaction that can occur within minutes of exposure to an allergen, most often from food, medication, or insect stings. It is almost always unexpected and can be life-threatening. Delay in clinical diagnosis and treatment can result in airway obstruction or cardiovascular collapse, which can turn fatal.

Treatment with epinephrine, also known as adrenaline, decreases the anaphylactic reaction. Adrenaline binds to a specific type of receptors, known as adrenergic receptors, and lessens the widening of blood vessels and blood vessel permeability induced by histamine (a substance in the body that causes allergic symptoms) during anaphylaxis. Adrenaline also relaxes the smooth muscles in the lungs. Administration of adrenaline during an anaphylactic reaction leads to better blood flow and improved breathing.

While epinephrine autoinjectors have been shown to be highly effective when properly used, some patients and caregivers delay or do not administer treatment in an emergency situation due to fear of the needle, lack of portability, or fear of people without medical training to give an injection, among others. The adrenaline nasal spray is absorbed rapidly by the nasal mucosa and distributed through the body.

For ethical and practical reasons, it was not feasible to conduct controlled clinical trials on Eurneffy's effectiveness in people experiencing a severe allergic reaction, but there is extensive information available about the use of adrenaline to treat severe allergy and it is currently the standard treatment for anaphylaxis. The efficacy and safety of Eurneffy were evaluated in 537 healthy people aged 19 to 55 years old enrolled in fourteen clinical studies. These trials compared Eurneffy with medicinal products where the adrenaline was injected intramuscularly and looked at the blood pressure and heart rate (pharmacodynamics), as well as at how the medicine is absorbed, modified and removed from the body (pharmacokinetics). The results demonstrate that the effects in the body of nasally-administered adrenaline are comparable to products given by an intramuscular injection.

No significant adverse events have been reported in clinical studies with Eurneffy. The most common adverse events were similar to those experienced with injections such as nausea, headache, throat irritation and dizziness, but also included nasal discomfort and a runny nose.

The CHMP recommended additional risk minimisation measures to reduce and prevent the potential risk of an inappropriate use of the device. These include training videos and other digital educational materials for patients, carers, and healthcare professionals. A training demonstration device of Eurneffy will also be available for these groups of people to simulate correct handling of the device.

The opinion adopted by the CHMP is an intermediary step on Eurneffy's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

EMA supports pilot for joint African continental assessment procedures

July 30, 2024

EMA has awarded a grant to the African Medicines Regulatory Harmonisation (AMRH) initiative of the African Union Development Agency (AUDA-NEPAD) to support a pilot to test procedures for the joint continental evaluation of medicines in Africa.

AUDA-NEPAD has been working on harmonisation activities for a decade, paving the way for the creation of the African Medicines Agency (AMA). The launch of the continental pilot is one of these activities that aim to validate procedures and processes ahead of the establishment of the AMA. The pilot, which is co-funded with the Bill & Melinda Gates Foundation, will run for a year.

During the pilot, the AMRH Evaluation of Medicinal Products Technical Committee (EMP-TC) will evaluate the quality, safety, and efficacy of priority medicinal products with the support of the continental Good Manufacturing Practices Technical Committee (GMP-TC). The learnings from the evaluations will help to develop continental processes and procedures, facilitate national authorisations of recommended medicines and strengthen information sharing and reliance.

The two AMRH technical committees visited EMA in June 2024 to share knowledge and get insights into EMA's regulatory procedures and processes, which could serve as possible model for the African continental regulatory system. EMA and the European medicines regulatory network (EMRN) will continue making available their unique experience and expertise in continental medicines regulation to support the establishment of the AMA by providing technical expertise and training both online and in person.

EMA's involvement in the AMA project officially started in December 2023 when the Agency received a contribution from the European Commission to support the setting up of the AMA. The project forms part of the European Union (EU) Global Gateway strategy and Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies.

The two most important keys on your keyboard

This is called the hash, pound, or number character. A hashtag is a keyword or set of keywords that is preceded by the # character. It is used in social media to create a thread of conversations around a specific theme or topic conveyed in short texts or microblogs. It is commonly used in Twitter, Instagram, YouTube, Pinterest, etc.

A dictionary of most common hashtags can be found at https://www.hashtags.org/definition/~h/.

For your info, EMWA is compiling a list of standarised hashtags for our social media use.

@ This is called the "at" sign or symbol. The @ sign is part of email addresses and social media user names ("handles"). Our EMWA handles are as follows: @Official_EMWA (Twitter), @EMWA (LinkedIn), and @europeanmedicalwritersassociation (Facebook)